

REMARKS

Status of the claims

Claim 1 is pending in the application.

Rejection under 35 U.S.C. §103

The Examiner maintains the position of the unpatentability of claim 1 under 35 U.S.C. §103, as being obvious over Yamamoto et al. combined with the newly cited reference of Mizoguchi et al. Mizoguchi et al. is relied upon for teaching a method of preparing *Lentinus edodes* mycelium using enzymatic digestion of the preparation.

Prior to addressing the substance of this rejection Applicants would like to clarify for the record that while the Examiner cites to page "628" of Mizoguchi et al. for the alleged relevant teaching, Applicants believe that the intended section of Mizoguchi et al. appears at page 460, right column, Item 2.

Mizoguchi et al. states that,

The disrupted material was incubated in water at 40-50°C for 60 hours to promote autolysis of the mycelia and partial digestion of the culture medium with mycelia enzymes. The digest was then extracted with water at 60°C.

However, there are several discrepancies in the teachings of the prior art with regard to the recited features of the invention of claim 1 that are not compensated for by Mizoguchi et al..

a) For example, the preparation of Mizoguchi et al. is digested with the mycelia enzymes, not "additive enzymes" as recited in claim 1. Nor is there any disclosure of specifically cellulase, protease or glucosidase in Mizoguchi et al.

b) In addition, there is no disclosure in Mizoguchi et al. of heating the extract to inactivate the enzymes. Mizoguchi et al. simply teaches incubating at 40-50°C and then extracting at 60°C.

The teachings of Mizoguchi et al. fail to make up for the deficiencies in Yamamoto et al., which the Examiner has herself noted, i.e. digestion with specific enzymes and heating to inactivate the enzymes. As such, the invention simply cannot be achieved by combining Mizoguchi et al. and Yamamoto et al. Applicants have previously shown in the record the

correlation between how a preparation is prepared (e.g. what enzymes are used) and the resulting product. As such, the disclosure of Mizoguchi et al. is insufficient to render the invention obvious when combined with Yamamoto et al.

On page 4 of the Office Action, the Examiner addresses Applicants' amendments and remarks of January 25, 2007 and notes the following points, each of which are addressed in turn.

1) The Examiner asserts that NK cells that are isolated from a patient will have a baseline cytotoxicity against the target cells. The Examiner asserts that activating NK cytotoxicity and enhancing LAK activity in the context of the invention are the same. However, the Examiner's position, in this regard, is technically incorrect.

As is defined in the present specification, "LAK activity" means the anti-tumor cytotoxic activity of cytotoxic T-lymphocytes, which attack tumors unrecognizable by lymphocytes having NK activity, but which have little influence on autologous normal cells (see page 7, line 28 to page 8, line 2 of the specification). The definition in the present specification demonstrates that "LAK activity" was considered in the art as being a different bioactivity from "NK cytotoxicity" at the filing date of the present application.

Further, the present specification defines that "LAK activity-enhancing" refers to the effect of enhancing this LAK activity, that is, inducing the production of LAK cells from lymphocytes or further enhancing the antitumor activity of existing LAK cells. On the other hand, "activating NK cytotoxicity" as mentioned by the Examiner is to increase cytotoxicity of NK cells against tumors which are recognizable and attacked by NK cells.

Thus, since it is generally considered by those skilled in the art that the LAK cells are a different population having different bioactivity from NK cells and that the target of "LAK activity" is completely different from that of "NK cytotoxicity", the Examiner's assertion is not correct.

2) The Examiner further states that the argument that the instant invention takes place *in vitro* is not given patentable weight because "it does not recite an active step". The Examiner is incorrect in this position because step (c) recites as an active step, "measuring and comparing" to a control sample to determine whether the extract has suitable a LAK-activity effect suitable for

the subject. Applicants respectively note that the recitation of the active form of the verbs, i.e. “measuring” and “comparing” are indicative of an active step.

Thus, for the reasons discussed above and the arguments presented on January 25, 2007, the instant invention is patentable over the disclosure of Yamamoto et al., when either considered alone or in combination with Mizoguchi et al. Withdrawal of the rejection is therefore respectfully requested.

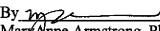
In view of the above Remarks, it is believed that claims are allowable.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By 
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